ARC Surgical, LLC 21300 NW Jacobson Rd, Hillsboro, OR 97124
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510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information: Arc Surgical LLC
21300 NW Jacobson Rd
Hillsboro, OR 97124
USA
Phone: (503) 645-9300
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Contact: Ed Boehmer, Regulatory Compliance Officer

DEC 27 2006

Classification Name:	Smooth or threaded metallic bone fixation fastener
Common Name:	Screw, Fixation, Bone
Proprietary Name:	Arc Surgical Bone Reduction Screw System
Proposed Regulatory Class:	Class II, 21 CFR 888.3040
Device Product Code:	HWC
Legally Marketed Equivalent Device(s):	Howmedica Osteonics Bosworth CC Screw K023294
	Zimmer Herbert Bone Screw K792022
	Stryker Leibinger TwinFix Screw K013775
	Biomet SS Cannulated Screw K984209

Device Description: The ARC Surgical Bone Reduction Screw is a headless, cannulated two-piece screw assembly. The two-piece design incorporates the use of a distal and proximal screw component. The implant is used to anatomically reduce two bone portions. The distal screw component engages the distal bone portion and the proximal screw component engages the proximal bone component.

Intended Use: The Bone Reduction Screw is intended to provide fixation and anatomically reduce two bones or bone portions. Specifically, these indications include scapholunate ligament repair, scapholunate reduction, lunotriquetral ligament repair, lunotriquetral reduction, and carpal instability.

These are similar to the intended use of predicate devices and do not raise new issues of safety and effectiveness.

Technological Characteristics: The screw is manufactured from 316L stainless steel per ASTM F-138.

Performance data is included in Section 10.
A discussion of clinical and non-clinical tests is not applicable.

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Based upon the similarities with the predicate devices, the safety and effectiveness of the ARC Surgical Bone Reduction Screw System is substantially equivalent to the predicate devices referenced.

Arc Surgical, LLC
% Mr. Ed Boehmer
Regulatory Compliance Officer
21300 NW Jacobson Road
Hillsboro, Oregon 97124

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Re: K063244
Trade/Device Name: Arc Surgical Bone Reduction Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 20, 2006
Received: October 26, 2006

Dear Mr. Boehmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K063244

Device Name: Arc Surgical Bone Reduction Screw System

Indications For Use:

The bone reduction screw is intended to provide fixation and anatomically reduce two bones or bone portions. Specifically, these indications include scapholunate ligament repair, scapholunate reduction, lunotriquetral ligament repair, lunotriquetral reduction, and carpal instability.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucher for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063244